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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,252	09/21/1998	RONALD MARK EVANS	SALK1470-2	8370

7590

02/27/2002

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EXAMINER

BUNNER, BRIDGET E

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/155,252

Applicant(s)

EVANS ET AL.

Examiner

Bridget E. Bunner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-20 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-20, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 16-20 and 22-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 14 December 2001 (Paper No. 10) has been entered in full. Claims 18-19 are amended, claim 21 is cancelled, and claims 27-28 are added.

This application contains claims 22-26 drawn to an invention nonelected with traverse in Paper No. 12 (02 March 2001). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-20 and 27-28 are under consideration in the instant application.

Sequence Compliance

1. The Applicant's response to the Notice to Comply with Sequence Listing Requirements under 37 CFR §1.821 (Paper No. 19, 14 December 2001) has been considered and is found persuasive. Therefore, the requirements set forth in the Notice to Comply (Paper No. 17, 15 August 2001) are *withdrawn*.

Withdrawn Objections and/or Rejections

2. The objections to the specification at pg 4 of the previous Office Action (Paper No. 17, 15 August 2001) are *withdrawn in part* in view of the amended specification (Paper No. 19, 14 December 2001). Please see section on Specification, below.

2. The rejection of claims 16-21 under 35 U.S.C. § 112, second paragraph at pg 7-9 of the previous Office Action (Paper No. 17, 15 August 2001) are *withdrawn in part* in view of

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Applicant's arguments and cancelled claims (Paper No. 19, 14 December 2001). Please see section on 35 U.S.C. § 112, second paragraph, below.

Oath/Declaration

4. The objection to the declaration regarding the issue of not identifying the post office address of each inventor is maintained and held in abeyance until allowable subject matter is identified.

Specification

5. The disclosure is objected to because of the following informalities:

5a. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). *An abstract on a separate sheet is required.* The basis for this rejection is set forth at pg 4 of the previous Office Action (Paper No. 17, 15 August 2001).

Applicant asserts that the present application is a national stage application of the corresponding PCT International application. Applicant contends that consistent with PCT practice, the abstract is provided on the cover sheet of the application. Applicant indicates that a copy of the abstract is enclosed on a separate sheet. Applicant's argument has been fully considered and is not found persuasive because a copy of the abstract was not received with Applicant's response of 14 December 2001 (Paper No. 19).

Claim Rejections - 35 USC § 112

6. Claims 16-20 and 27-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Claims 16-20 and 27-28 are directed to a method of testing a compound for its ability to regulate transcription-activating effects of a peroxisome proliferator activated receptor-gamma (PPAR- γ) comprising assaying changes in the level of reporter protein as a result of contacting cells containing the receptor and reporter vector with a compound. Further, the claims recite that the reporter vector comprises a promoter, hormone response element, and a DNA segment encoding a reporter protein. The compound is a putative antagonist for the peroxisome proliferator activated receptor-gamma and the cell contacting is carried out in the presence of increasing concentrations of the compound and a fixed concentration of at least one agonist. The claims also recite that the cell contacting is carried out in the presence of at least one PPAR- γ -agonist or antagonist. The basis for this rejection is set forth for originally filed claims 16-21 at pg 5-7 of the previous Office Action (Paper No. 17, 15 August 2001).

Applicant's arguments (Paper No. 19, 14 December 2001), as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant asserts that Examples 1-4 in the specification provide substantial guidance with respect to various aspects of the claimed invention. Applicant contends that Example 1 describes the preparation of a GAL4-receptor fusion protein. Applicant argues that the process described in Example 1 is useful for generating a number of chimeric species, including GAL4-PPAR- γ , and that those skilled in the art would not require "a large quantity of experimentation" to practice this aspect of the invention. Applicant states that Example 2 provides ample guidance regarding the preparation of reporter constructs and therefore, a "large quantity of experimentation" is not required to practice this aspect of the invention. Applicant asserts that Example 3 describes in detail a screening assay for identification of receptor selective agonists

and that those skilled in the art would readily acknowledge that a “large quantity of experimentation” is not required to practice this aspect of the invention. Applicant also argues that Example 4 describes the measurement of dose responses of GAL4-PPAR- γ constructs to various compounds (prostaglandins).

Applicant's arguments have been fully considered but are not found to be persuasive. Although Examples 2-3 describe the preparation of various reporter constructs and screening assays and one skilled in the art would be familiar with these preparation and screening methods, the skilled artisan would not know the elements encompassed by the pTK-MH100x4-LUC construct utilized in Examples 2-3. There is a lack of guidance in the specification regarding whether or not the pTK-MH100x4-LUC construct contains any hormone response elements. Furthermore, undue experimentation would be required of the skilled artisan to determine the specific sequence and the number of repeats of the hormone response element, if it is present in the pTK-MH100x4-LUC reporter construct. Although Example 3 teaches co-transfecting CV-1 cells with CMX-GAL-PPAR- γ and pTK-MH100x4-LUC and incubating the cells with various agonists, the specification does not teach contacting the cells with at least one antagonist. The specification does not disclose contacting the cell that contains the receptor of interest and the reporter vector with a fixed concentration of agonist concomitantly with increasing concentrations of any compound. There is a lack of guidance in Example 4 of the specification regarding which reporter plasmid is transfected into CV-1 cells. Additionally, the specification provides little guidance regarding what sort of compounds should be screened for the transcription-activating effects of a PPAR- γ and therefore, the skilled artisan must resort to trial and error experimentation to determine which class of compounds might yield one with the

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desired activity. Such trial and error experimentation is considered undue. Please note that Applicant's argument of a "large quantity of experimentation" is only one factor to be considered under a 35 U.S.C. § 112, first paragraph, enablement rejection.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to determine the sequence of the optimal response element and to regulate transcription activation of PPAR- γ by assaying the levels of a reporter protein wherein the reporter vector comprises a promoter, a hormone response element, and a DNA segment encoding the reporter, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the incubation of a PPAR- γ /reporter vector cell with any compound and any agonist or antagonist, the complex nature of the invention, and the breadth of the claims which fail to recite any hormone response element limitations and agonist/antagonist/compound limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

35 USC § 112, second paragraph

7. Claims 16-20 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Claims 16-20 and 27-28 are indefinite because the claims do not have a step that clearly relates back to the preamble. For example, there is no step indicating how the level of a reporter protein has to change in order to determine that the test compound regulates transcription-activating effects of a PPAR- γ . Does the reporter protein increase? Decrease? Remain the

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same? The basis for this rejection is set forth for originally filed claims 16-21 at pg 7-8 of the previous Office Action (Paper No. 17, 15 August 2001).

Applicant's arguments (Paper No. 19, 14 December 2001), as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant asserts that there is no statutory requirement that a claim drawn to a method must have a step relating back to the preamble. Applicant also indicates that with respect to the level of reporter protein, claim 16 recites that one merely must determine if a test compound causes a change in the level of reporter protein to conclude that a test compound regulates transcription-activating effects of PPAR- γ .

Applicant's arguments have been fully considered but are not found to be persuasive. Since the goal set forth in the preamble is not what occurs when one carries out the method steps, it is unclear what is required by the claim. Furthermore, as mentioned in the rejection restated above, it is not clear how the level of a reporter protein specifically has to change. Does the reporter protein level increase if the transcription-activating effects of PPAR- γ is regulated by a compound as compared to control? Does the reporter protein level decrease if the transcription-activating effects of PPAR- γ is regulated by a compound as compared to control?

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Conclusion

No claims are allowable.

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Evans et al. U.S. Patent No. 5,861,274

Evans et al. U.S. Patent No. 5,939,442

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BEB
Art Unit 1647
February 14, 2002

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER